

March 23, 1999

Ms. Hortense L. Macon  
Indirect Additives Branch, HFS - 216  
Division for Petition Control  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

**Re: Food Additive Petitions FAP 5B4450 and 5B4451 (Shell Chemical Company),  
Docket Nos. 95F-0129 and 95F-0130**

Dear Ms. Macon:

We are writing to you on behalf of several soda ash manufacturers and several members of the Sand Institute to express our concern with respect to the above petitions and with respect to an October 30, 1998 letter sent to you by NAPCOR<sup>1/</sup> regarding the above petitions. These petitions cover the use of naphthalate and copolymer blends in packaging applications.

Our companies have a collected interest in glass manufacturing and glass packaging markets (soda ash and sand are primary ingredients in glass manufacturing). We believe the comments provided herein are pertinent and relevant to the above petitions and should be given equal and serious consideration. Despite calls from NAPCOR and other special interest groups to expeditiously approve the above petitions, we encourage the FDA to conduct it's review with deliberate caution given the poor state of plastic recycling and our objections to information contained within the Shell petitions.

To start, we would like to address some of the content contained in the October 30, 1998 NAPCOR letter. First, NAPCOR's statement: "The growth of PET recycling has been astounding" is intended to grossly mislead the reader to conclude that the state of plastics recycling is healthy. This is not true. In the past decade, over 13 times more virgin plastic packaging was produced than was recycled.<sup>2/</sup> Such a statement overshadows the true potential

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<sup>1/</sup> See October 30, 1998 letter from the National Association for PET Container Resources ("NAPCOR") to Ms. Hortense Macon.

<sup>2/</sup> See "Environmental Defense Fund exposes "sorry state" of plastics recycling: Analysis uses industry's own numbers" *San Diego Earth Times* (January 1998).

95F-0129

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environmental impact that would result from the approval of these petitions. As we will discuss later, we also contend that the petitions themselves have attempted to minimize the environmental impact in order to expedite the review process.

Second, NAPCOR concludes that polyethylene naphthalate ("PEN") will not hurt the polyethylene terephthalate ("PET") recycle stream. In small quantities this statement has been supported with scientific evidence. However, the very market which PET/PEN blends target (beer container) is no small market. Recently, the vice-president of Eastman's container plastics division was quoted as saying: "If we only convert half of the packaged beer market to PET containers, it would double (the world) demand for PET."<sup>3/</sup>

Finally, NAPCOR argues that in the event PEN does pose a problem to PET recycle, technology has been developed to separate PEN from PET. There is no discussion on whether the economics of this technology is viable. The very characteristics that make plastics so desirable for packagers; lightweight, unbreakable and moldable; are a detriment when it comes time to collect and transport them for recycle.

As for the Shell petitions, we are writing to express our concern that the Environmental Assessments ("EAs") submitted by Shell Chemical Company in support of the above-referenced food additive petitions,<sup>4/</sup> do not adequately reflect the environmental impacts that could result if FDA approves the petitions. In particular, Shell has substantially understated the size of the potential market for the PET/PEN blends that are the subjects of the petitions, and has overstated the likely extent of their recycling. Whatever the accuracy of Shell's market assumptions at the time of the petitions' 1994 submission (and we believe that the market estimates were low even then), subsequent developments demonstrate that the potential market is far larger than reflected in Shell's filings. The problems created by the understating of the potential market are compounded by overly optimistic assertions regarding the new blends' anticipated effects on recycling. As a result, the potential effects of approval of Shell's petitions on the disposal and recycling of food packaging are substantially understated.

FDA is obligated under the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 *et seq.*, and the Council on Environmental Quality and FDA regulations implementing NEPA, 40 C.F.R. Parts 1500-08 (CEQ) and 21 C.F.R. Part 25 (FDA), to evaluate carefully the environmental impacts of its actions, including its decisions on food additive petitions such

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<sup>3/</sup> See "PET Makers Eye New Applications & More Growth: Plastic beer bottles are being introduced and could expand the market rapidly" *Chemical Market Reporter* (November 23, 1998).

<sup>4/</sup> See Shell Chemical Co., Appendix VII -- Environmental Assessment for Food Additive Petition Terephthalate/Naphthalate Polymers, Docket No. 95F-0130 (Dec. 20, 1994); and Shell Chemical Co., Appendix VII, Environmental Assessment for Food Additive Petition Naphthalate/Terephthalate Polymers, Docket No. 95F-0129 (December 28, 1994) (hereafter "Shell EA's").

as Shell's. The environmental review must take into account new and updated information,<sup>5/</sup> and we therefore request that the FDA give careful consideration to the points raised below.

Earlier this year, Wellman, Inc. advised FDA that, despite its earlier concerns regarding the potential impact of PEN copolymers and blends on post-consumer PET recycling,<sup>6/</sup> it is now withdrawing those concerns after working closely with Petitioner Shell Chemical and others on an automated sorting system for which two trials have been conducted at a Wellman pilot plant.<sup>7/</sup> Wellman also reported that it had been made aware of "trial data" indicating that its concerns about the effect of PEN on the dyeability of the fibers that are the primary use of recycled PET "may not be a significant issue."<sup>8/</sup> NAPCOR's comments similarly argue that recent research supports the conclusion that PET/PEN blends "can be compatible with the post consumer PET recycling stream."<sup>9/</sup> At first glance, such comments, coupled with the assertions in Shell's December 1994 EA's, would appear to support a conclusion that the environmental impacts of approving Shell's petitions would be minor. Closer examination, however, reveals that the solid waste disposal impacts of the PET/PEN blends could be significant and must therefore be carefully analyzed by FDA.

Shell's argument that disposal of containers made with the new blends will not be a major problem rests on three premises: first, that the blends will not achieve sufficient market penetration to affect the municipal solid waste stream in a significant way; second that the recyclability of PET will not be adversely affected by being blended with PEN; and third, that there is sufficient demand for recycled PET (or PET/PEN) to avoid increased landfill disposal of PET/PEN containers. However, the validity of each of these premises is open to significant

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<sup>5/</sup> Cf. 40 C.F.R. § 1502.9(c) (requiring supplementation of environmental impact statements to reflect new circumstances). See *Friends of the Bow v. Thompson*, 124 F.3d 1210, 1218 n.3 (10<sup>th</sup> Cir. 1997) (United States and environmental organization plaintiff agreed that the updating standards of 40 C.F.R. § 1502.9(c) apply to EA's as well as to full environmental impact statements); see also *Price Road Neighborhood Ass'n v. U.S. Dept. of Transp.*, 113 F.3d 1505, 1510 (9<sup>th</sup> Cir. 1997) (Federal Highway Administration standards for supplementation of an EA); *Bicycle Trails Council of Marin v. Babbitt*, 82 F.3d 1445 (9<sup>th</sup> Cir. 1996) (National Park Service prepared a supplemental EA following public review of original EA).

<sup>6/</sup> See November 18, 1996 letter from Wellman, Inc. to FDA's Dockets Management Branch, expressing concern about PEN's adverse effects on the dyeability of recycled PET fiber and the lack of automatic sorting technology to separate PEN from PET to avoid the problem.

<sup>7/</sup> See May 19, 1998 letter from Wellman, Inc. to FDA's Dockets Management Branch.

<sup>8/</sup> *Id.*

<sup>9/</sup> NAPCOR letter at 1.

question, and the questions have become more substantial in the time since Shell's petitions were filed.

**1. The potential market for the PET/PEN blends is far larger than Shell's Environmental Assessments suggest.**

The EA's submitted by Shell in support of its petitions contain a number of statements suggesting that the anticipated markets for packaging made with the PET/PEN is a small one.<sup>10/</sup> Shell therefore argues that any environmental consequences attributed to the polymer blends need not be of concern. In fact, however, the market is substantial, requiring that FDA closely scrutinize the effects that would flow from approval of Shell's petitions.

It can not be questioned that, when suitable plastics have been approved by FDA for food packaging uses, they have made significant and rapid inroads into markets in which other forms of packaging, such as glass or aluminum, historically predominated.<sup>11/</sup> PET packaging has been a major factor in the rise in plastic packaging, with use for soda bottles, peanut butter, and other products. However, PET's ability to penetrate other markets has been limited by properties that make it unsuitable for products that must be packaged at high temperatures or that require stronger gas barrier properties.<sup>12/</sup> It is precisely these limitations that will be lifted by combining PET with PEN.<sup>13/</sup>

To take one example, considerable attention has been given to the possibility of using PET/PEN blends for beer bottles,<sup>14/</sup> for which strong gas barrier performance is needed.. Other potential uses that have been identified include baby food, jellies and jams, mayonnaise,

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<sup>10/</sup> See Shell EA's at VII-4 (FAP 95F-0129), VII-3 (FAP 95F-0130) ("Shell estimates that the market for terephthalate/naphthalate polymers will be a small fraction of the current and future markets for PET.") and VII-11 ("The maximum yearly volumes for the proposed applications are provided in the Confidential Appendix IV of this petition. They constitute a very small fraction (less than 1 percent) of existing uses of polyester polymers.").

<sup>11/</sup> See U.S. EPA, *Characterization of Municipal Solid Waste in the United States: 1997 Update*, Report No. EPA530-R-98-007 (May 1998) (hereafter "EPA 1997") at 33-34, 38, 69, 96, 136

<sup>12/</sup> See Shell EA's at VII-2 - VII-3.

<sup>13/</sup> *Id.*

<sup>14/</sup> See, e.g., "Outlook Improving for Plastic Beer Bottles," *Plastics News* (Aug. 17, 1998); "Consumers Warm Up to a Cold One in Plastic: Problems Remain for PET, PEN in Beer Bottles," *Plastics News* (Apr. 27, 1998); "PET Forecast: Dynamic Front Moving In; Polyester Packaging Industry," *Beverage World Periscope Edition* (Mar. 31, 1998); "Report Uncovers PET Potential for Beers," *Packaging Week*, (Sept.18, 1997).

pickles and relishes and sauces.<sup>15/</sup> The beer market alone accounted for an estimated 5,540,000 tons of packaging in 1996, or more than three times the amount of packaging accounted for by soft drinks. *See* EPA 1997 at 101. The potential market for the PET/PEN blends thus substantially exceeds the modest expectations reflected in Shell's environmental assessments.

In the face of the enormous potential PET/PEN market, Shell has argued that the currently high relative cost of PEN will limit the extent to which that market can be penetrated.<sup>16/</sup> However, Shell's 1994 pricing snapshot can not be taken as a reliable prediction of the economics that would follow an FDA approval of the blends. As demand for the blends increases (not only for the food packaging uses covered by Shell's petitions but also for other applications<sup>17/</sup>) and production capacity grows, prices are expected to drop, reducing or eliminating barriers to the use of PET/PEN blends in a variety of markets. One recent prediction is that PEN prices will drop from their current level of \$4.00 per pound to about \$2.00 or \$2.50 per pound as production capacity for PEN and its NDC monomer feedstock increases.<sup>18/</sup>

Indeed, that capacity is already increasing. For example, Shell's 1994 EA's noted that Amoco Chemical Company's Decatur, Alabama facility, with a design capacity of 60 million pounds, would begin production of the NDC feedstock in 1995.<sup>19/</sup> According to press reports in late 1997:

Over 6 months ahead of schedule, the . . . (NDC) Decatur, AL plant of Amoco Chemical, achieved full design capacity of 60 M lbs/y in Jul 1997. . . . Amoco has plans to raise the capacity at its Decatur, AL plant to between 90-100 M lbs by 1999. Early in the new century a new NDC plant will be built.<sup>20/</sup>

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<sup>15/</sup> "Kline Study Predicts Success for PEN Once Manufacturing Costs Drop," PR Newswire (April 27, 1998).

<sup>16/</sup> *See* Shell EA's at VII-3 (FAP 95F-0130), VII-2 - VII-3 (FP 95F-0129) ("There is significantly higher cost for the raw material, so economics are expected to severely limit the use of terephthalate/naphthalate polymers to those applications where the physical properties are sufficiently desirable.")

<sup>17/</sup> Shell EA's at VII-5.

<sup>18/</sup> "Kline Study Predicts Success for PEN Once Manufacturing Costs Drop," PR Newswire (April 27, 1998).

<sup>19/</sup> Shell EA's at VII-6 (FAP 95F-0130), VII-5 (FAP 95F-0129).

<sup>20/</sup> "Amoco Starts up NDC Unit, Sets Plans for Second Big Plant," *Chemical Business Newbase* (Nov. 14, 1997). *See also* "PEN Market Poised to Take Off with Startup of Feedstock Unit," *Chemical Market Reporter* (Sept. 29, 1997).

According to an Amoco spokesperson, the new NDC plant is expected to be "significantly larger than our current plant. We are anticipating demand growing significantly in all the market segments."<sup>21/</sup> Thus, even without FDA approval of Shell's petitions having yet occurred, rapid expansion of capacity is taking place.

In addition, Shell's discussion of the high cost of PEN fails to address the fact that the subject of the pending petitions is not PEN homopolymer, which has already been approved by FDA, but blends of PEN with the less expensive PET.<sup>22/</sup> Obviously, a higher cost for a low percentage component is far less of a limiting factor than a similarly high cost for a material that is the sole component of a package. PET/PEN has already been introduced for soft drink bottles in Europe,<sup>23/</sup> carbonate juice bottles in Japan,<sup>24/</sup> and beer bottles in Australia,<sup>25/</sup> suggesting that cost is not an insurmountable problem.

In short, Shell substantially understates the extent to which the PET/PEN blends are likely to be used if approved by FDA.

**2. The effects on food packaging recycling and disposal have not been adequately addressed.**

Shell acknowledges that if the new polymer blends significantly displace competing packaging materials, the "efficiencies and economics" of current municipal solid waste management could be affected.<sup>26/</sup> It argues, however, that market penetration will be too small to bring about such shifts and their likely environmental consequences.<sup>27/</sup> Thus, the environmental assessments' failure adequately to reflect the potential size of the PET/PEN market means that they also fail to provide adequate assurance that approval of the PET/PEN blends for food packaging will not adversely affect recycling programs or result in a substantial increase in the

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<sup>21/</sup> "Amoco NDC Plant Achieves Full Capacity Ahead of Projection; Expansion Planned for 1999," *PR Newswire* (Sept. 15, 1997).

<sup>22/</sup> PEN content is expected to be "substantially less than 50% for the vast majority of applications." Shell EA (FAP 95F-0130) at VII-25.

<sup>23/</sup> "Acts of Creation," *Packaging Week* (Dec. 11, 1997).

<sup>24/</sup> "Mitsubishi Plastics Making PET Bottles with 8% PEN Content," *COMLINE Daily News Chemicals and Materials* (Sept. 22, 1987).

<sup>25/</sup> "Sidel-GEBO Pact May Tap Beer Market," *Plastics News* (July 28, 1997).

<sup>26/</sup> Shell EA's at VII-12.

<sup>27/</sup> *Id.*

amount of packaging waste for which landfill disposal or incineration is necessary. Among the questions and issues raised by the materials filed to date are the following:

- Shell's environmental assessments assert that the inclusion of PEN should not affect the recyclability of PET and that it expects PET/PEN containers to be "readily recycled." *See, e.g.*, Shell EA's at VII-13 - VII-17. Shell's assertions are, however, largely speculative or based on the assumption that existing PET recycling practices can continue and can accommodate PEN without any changes. However, the limited data cited by Shell with respect to recycling of material actually containing both polymers appear to have dealt only with one mix of polymers (in that case, 6% PEN content) and, in Shell's own words, were "too limited to provide broad, definitive evidence to either endorse or disapprove of naphthalate-containing recycle feedstocks."<sup>28/</sup>
- Similarly, the testing described in the NAPCOR comments reached conclusions only with respect to blends containing very low levels of PEN, even though the Shell petitions would cover PET/PEN blends in any combination. For example:
  - ⇒ "PET bottle-to-bottle recycling should not be impacted by the presence of naphthalate containing polymers that result in less than 3 mole % NDC in the recycle stream and only slight adjustments may be needed to make commercial quality bottles at up to 6 mole % NDC in the recycle stream."<sup>29/</sup>
  - ⇒ "NPC believes that bottle-to-fiber recycling into non-dyed fiber applications is not impacted by the presence of up to 10% NDC in the recycle stream. For dyed fiber applications, no impact on appearance is expected at naphthalate levels of approximately 4% and lower in carpet applications and below approximately 1½ % to 2½ % in textile applications depending on the dyeing process used."<sup>30/</sup>
  - ⇒ These limited test results do not address the majority of the possible PET/PEN blend ratios that would be permitted if Shell's petitions were approved.
- Wellman's recent letter withdrawing its previous concerns about the recyclability of the PET/PEN blends states that Wellman is now satisfied, based on the results of two trials of an automated sorting system for PEN containers, that "the technology to sort PEN containers from the PET stream, if required, is technically viable. . ." Similarly, the NAPCOR comments and enclosures report that sorting technology can successfully

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<sup>28/</sup> Shell EAs at VII-29. *See generally id.* at VII-25 - VII-30.

<sup>29/</sup> *See* Naphthalate Polymer Council ("NPC") Position Statements (enclosed with NAPCOR letter) at 1.

<sup>30/</sup> *Id.* at 1.

separate blends with PEN levels higher than suitable for PET recycling.<sup>31/</sup> Is the technology economically as well as technically viable? How will the containers diverted from the PET stream be disposed of? Is there adequate disposal capacity for a substantial number of such containers?

- One of the largest potential markets for PET/PEN blends – beer bottles – is currently one of the few markets with a significant level of refillable/reusable containers. EPA 1997 at 96. What would be the environmental impacts of replacing these bottles with plastic bottles?
- Shell's assertion that landfill capacity would not be adversely affected by approval of its petitions appears to assume that the new PET/PEN containers would be disposed of at the same rate and in the same manner as the packaging they replace.<sup>32/</sup> Such an assumption is unfounded. According to EPA, aluminum packaging is recycled at a much higher rate than even PET homopolymer. Although EPA's glass container recycling rates nominally appear lower than for PET containers, the recycling rates do not include the glass containers that are reused or refilled (which EPA considers "source reduction" rather than "recycling"). When the reuse/refill levels are included, the reuse/refill/recycle rate is approximately the same as the PET container recycling rate with refillable bottles typically being used eight times<sup>33/</sup> before recycling or disposal. *See generally* EPA 1997 at 33-42. Thus, even if PEN does not adversely reflect recyclability of the PET with which it is combined -- and that has not been adequately established -- a PET/PEN container is more likely than the container it replaces to end up in the waste stream. If, as described above, the potential PET/PEN displacement of glass and aluminum packaging is substantial, there could be a significant effect on waste disposal capacity that has not yet been addressed.

**3. Demand for an increased volume of recycled plastics has not been demonstrated.**

Even if recycling of PET/PEN is technologically feasible and will not adversely affect existing PET recycling capability, as asserted by Shell, Wellman, and NAPCOR, recycling will not occur (or will be unsuccessful in diverting materials from landfills or incinerators) if there is not an adequate market for the recycled plastic. In analyzing the potential demand for

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<sup>31/</sup> See NAPCOR letter at 1 and *id.* at 6 - 7.

<sup>32/</sup> Shell EAs at VII-31. ("The approval of the proposed food additive is not expected to cause any significant changes in the landfill volume required to dispose of food-packaging articles. Since packaging made from the proposed food additive would replace packages made from competing materials, net changes would be minimal.")

<sup>33/</sup> EPA 1997 at 96



recycled packaging materials, it is important to note that a key difference between the recycling of PET and of other packaging materials. As described by EPA:

Like the other basic industries discussed in this chapter, production of plastic resins is an important part of the U.S. economy. With respect to recycling, however, there are important differences. Other materials producers (e.g., the paper, glass, and steel industries) can and do use recovered postconsumer materials as raw materials in their plants, with or without the addition of virgin raw materials. For technical reasons, plastic resin producers rarely do the same.

Recovered plastic products are usually sent to a reclaimer, who sorts, grinds, cleans, dries, and pelletizes the plastics. . . .After processing, the pellets can be sold to a fabricator to be made into a new product. The pellets are not returned to a virgin resin plant. Therefore, capacity to make virgin resin does not provide a market for recovered resin.

EPA 1997 at 147-48.

Not only is there not generally a market for recovered PET among virgin materials producers, the types of products for which manufacturers will purchase recycled PET are limited. Alternate packaging materials, such as glass or aluminum, that would likely be displaced by the PET/PEN blends can be recycled back into food packaging or for other uses. For example, EPA has noted that:

[c]ontainer glass is a versatile recyclable material. Aside from color, the properties of container glass cullet (crushed glass) are common to the various glass containers. For example, color sorted cullet from a pickle jar can be used in the fabrication of a soft drink or perfume container of the same color.

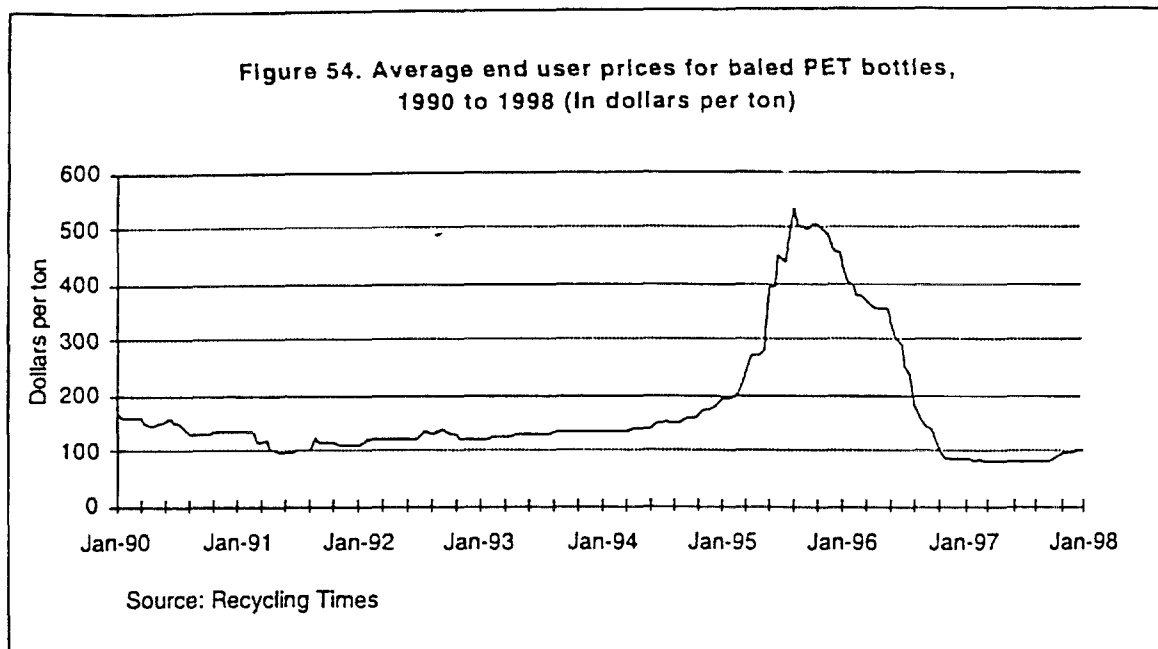
EPA 1997 at 136. Accordingly, most glass recovered from containers goes into other containers, *id.* at 35, and glass recycled content has increased. *Id.* at 136-37. Despite the decreased market shares for glass containers, EPA expects that the “demand for quality color-separated cullet will continue to be sound.” *Id.* at 138.

Similarly, most recovered aluminum beverage cans are recycled into new cans, although there are other uses as well. *Id.* at 139. Both recycling rates and recycled content rates for aluminum containers are quite high: aluminum packaging recovery has been 50 percent or higher since 1981 (with some categories of packaging, such as soda cans reaching even higher rates, *id.* at 6) and recycled content of new aluminum containers reaching 51.6% in 1996. *Id.* Although demand for aluminum packaging, like that for glass containers, has suffered from the increased use of PET packaging, *id.* at 141, EPA concludes that “[a]luminum markets can absorb more material, either in new beverage cans by increasing the recycled content or in other markets such as aluminum casting, extrusion, or exports. . . .” *Id.* at 139.

In contrast, recycled PET containers are generally “downcycled,” *i.e.*, primarily marketed for uses other than containers, principally fiber for carpets, insulation, sleeping bags and the like.

*Id.* at 146-48; Shell EA’s at VII-26 - VII-31. This means, first, that the significant increase in plastic food packaging that would be expected upon FDA approval of PET/PEN blends will not be absorbed as recycled content in comparable packaging; the fiber and related markets will have to be large enough to accommodate the increased supply. However, even if inclusion of PEN in the fiber does not adversely affect market demand -- and, so far, Wellman has only stated that it has “been made aware of *trial* data that indicates that the effect of PEN fluorescence on recycled PET fibers *may* not be a significant issue for the public consumer”<sup>34/</sup> -- that demand does not appear sufficient to support existing PET recycling, much less the recycling of the substantially increased quantity of plastic food packaging that would likely result from substitution of PET/PEN for other packaging materials.

Shell’s environmental assessments stated that demand for recycled plastic was strong and increasing.<sup>35/</sup> However, since December 1994, when Shell’s assessments were filed, the market for recycled PET has peaked and fallen dramatically, as illustrated in the following graph.



<sup>34/</sup> See May 19, 1998 letter from Wellman, Inc. to FDA’s Dockets Management Branch (emphasis added).

<sup>35/</sup> See Shell EA’s at VII-17 (“Recycling demand is expected to exceed supply for the next several years so that interest in expanding the PET recycling stream is likely to continue.”)

EPA 1997 at 147, Fig. 54. EPA commented that, compared to the demand for high density polyethylene ("HDPE"),

[m]arket factors for PET are less favorable. Due to the increased popularity of PET beverage bottles, the industry geared up for increased production. There is currently an over-capacity for virgin PET resin, reducing its price structure and providing off-class virgin which competes with recycled PET for the same markets. Not only has the U.S. developed a large capacity, but China, Korea, and Taiwan, consumers of U.S. postconsumer PET, have been increasing their virgin capacity. This further reduces demand for U.S. recovered PET.


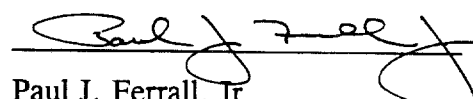


There has also been a weakening or sunset of plastic recycling laws in some states. For example, legislation in Florida changed, reducing the demand for recovered PET.

*Id.* at 148. Thus, the only realistic expectation is that substantial numbers of the new PET/PEN containers will be disposed of, and the Shell environmental assessments have not adequately addressed the environmental impacts of that disposal.

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We urge you to give careful consideration to the above issues and to ensure that the potential environmental impacts of the use of PET/PEN blends for food packaging are fully evaluated.

Sincerely,

  
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